REMARKS

The following remarks are responsive to the Office Action dated August 26, 2005. Applicant has not made any amendments to the claims by way of this response. Claims 1-41 remain pending.

Claim Rejections Under 35 U.S.C. § 102

In the Office Action, the Examiner rejected claims 1-3, 5, 9, 12, 14-17, 21, 26-31, 33-34, 37-39 and 41 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,416,480 to Nenov (Nenov). Applicant respectfully traverses these rejections. Nenov fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

Claims 1-3, 5, 9, 12 and 14

For example, Nenov fails to teach or suggest selecting a brain injury protocol as a function of received data concerning a patient, as required by Applicant's independent claim 1. Instead, Nenov teaches a system for automatically acquiring patient data for a single, predetermined patient evaluation metric, the Glascow Coma Score (GCS). (E.g., Abstract, col. 1, ll. 16-20, col. 5, ll. 51-53). Nenov does not suggest that the system selects GCS from among other possible evaluation metrics, or a technique for determining the GCS from among a number of possible techniques. In other words, Nenov does not suggest that the apparatus in any way selects a protocol, much less selects a brain injury protocol as a function of received data concerning a patient, as required by claim 1.

In rejecting claim 1, the Examiner cited col. 1, ll. 13-20 of Nenov, which in relevant part states:

> The present invention relates to systems and methods for computerized monitoring [of] the levels of consciousness of patients...[that] automates and ultimately completely eliminates the need for human assessment of the most commonly used coma score – the Glascow Coma Score (GCS)....

This passage from Nenov does not support the Examiner's argument that Nenov teaches selecting a brain injury protocol as a function of received data concerning a patient. On the contrary, the cited passage emphasizes that Nenov is directed to a system for automatically

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acquiring patient data for a single, predetermined patient evaluation metric – the Glascow Coma Score (GCS).

As another example, Nenov fails to teach or suggest selecting a brain injury protocol as a function of data received from an operator concerning a patient, as required by claim 2. In rejecting claim 2, the Examiner argued that "Nenov discloses a method comprising 'receiving data concerning a patient.'" In support of this argument, the Examiner cited col. 9, ll. 60-64 of Nenov, which indicates that a nurse may prerecord verbal stimuli, e.g., speak the patient's name, that will later be provided to a patient for automatic determination of the GCS. However, Nenov does not even remotely suggest that this prerecorded stimulus is used to a select a brain injury protocol, as required by claim 2.

Nenov fails to disclose each and every limitation set forth in claims 1-3, 5, 9, 12 and 14. For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicant's claims 1-3, 5, 9, 12 and 14 under 35 U.S.C. § 102(b). Withdrawal of these rejections is requested.

Claims 15-17

Like independent claim 1, independent claim 15 requires selecting a brain injury protocol as a function of received data concerning a patient. As discussed above, Nenov fails to teach or suggest this requirement of claim 15. Further, like claim 2, independent claim 15 requires that the data comprise data received from an operator. In other words, like claim 2, independent claim 15 requires selecting a brain injuring protocol as a function of data received from an operator. As discussed above with reference to claim 2, Nenov fails to teach or suggest this requirement of claim 15.

Nenov also fails to teach or suggest presenting a checklist to the operator, the checklist requiring entry of data concerning a neurological condition of a patient. In contrast to this requirement, Nenov teaches the advantages of a system that automatically determines the Glascow Coma Score for a patient, without user intervention. (E.g., Abstract, col. 1, ll. 16-20, col. 5, ll. 51-53). Accordingly, Nenov would not have even suggested this requirement of independent claim 15 to one of ordinary skill in the art.

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Nonetheless, the Examiner argued that this requirement was explicitly disclosed in Nenov. In particular, the Examiner argued that the computer of the Nenov system is an operator, and the algorithm executed by the computer, represented by FIGS. 4A and 4B, is a checklist. This interpretation is erroneous in at least two respects.

First, interpreting an algorithm executed by a computer, as described by Nenov, to anticipate a checklist presented to an operator requesting entry of data concerning a neurological condition of a patient, as required by claim 15, is unreasonable. The computer of the Nenov system is not an "operator" of the system. Instead, the computer is a component of the system. Moreover, algorithm represented by FIGS. 4A and 4B is not a checklist that requests entry of data, or presented to the computer, as recited in claim 15. Instead, the algorithm merely describes the various activities performed by the computer over time.

Second, the Examiner's interpretation of the term "operator" for this limitation of claim 15 is inconsistent with the Examiner's interpretation of the term "operator" for the "receiving the data from the operator" limitation. In particular, the Examiner has interpreted the term "operator" to refer to a computer in the "presenting" limitation, and a nurse (person) in the "receiving" limitation.[1] It is improper to interpret a term inconsistently within a claim.[2]

Nenov fails to disclose each and every limitation set forth in independent claim 15. For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicant's claims 15-17 under 35 U.S.C. § 102(b). Withdrawal of these rejections is requested.

Claims 21 and 26-31

Similar to independent claims 1 and 15, independent claim 21 requires a processor to select a brain injury protocol as a function of received data. For the reasons discussed above with reference to claim 1, Nenov fails to teach or suggest this requirement of independent claim 21. For at least this reason, the Examiner has failed to establish a prima facie case for anticipation of Applicant's claims 21 and 26-31 under 35 U.S.C. § 102(b). Withdrawal of these rejections is requested.

[1] Applicant notes that the nurse described in Nenov is also not an "operator" of the Nenov system. As described at col. 9, ll. 60-64, the nurse merely preconfigures the Nenov system for its later, automatic operation.
[2] *See, e.g.*, Phonometrics, Inc. v. Northern Telecom Inc., 45 U.S.P.Q.2d 1421, 1426 (Fed. Cir. 1998).

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Claims 33, 34 and 37

Similar to independent claim 1, independent claim 33 requires a medium comprising instructions that cause a programmable processor to select a brain injury protocol as a function of received data concerning a patient. For the reasons discussed above with reference to claim 1, Nenov fails to teach or suggest this requirement of independent claim 33. For at least this reason, the Examiner has failed to establish a prima facie case for anticipation of Applicant's claims 33, 34 and 37 under 35 U.S.C. § 102(b). Withdrawal of these rejections is requested.

Claims 38, 39 and 41

Similar to independent claim 15, independent claim 38 requires a medium comprising instructions that cause a programmable processor to present a checklist to an operator, the checklist requesting entry of data concerning a neurological condition of a patient, receive the data from the operator, and select a brain injury protocol as a function of the data. For the reasons discussed above with reference to claim 15, Nenov fails to teach or suggest these requirements of independent claim 38. For at least this reason, the Examiner has failed to establish a prima facie case for anticipation of Applicant's claims 38, 29 and 41 under 35 U.S.C. § 102(b). Withdrawal of these rejections is requested.

Claim Rejection Under 35 U.S.C. § 103

In the Office Action, the Examiner also rejected: claims 4, 18 and 32 under 35 U.S.C. § 103(a) as being unpatentable over Nenov in view of U.S. Patent No. 6,406,427 to Williams et al. (Williams); claim 6 under 35 U.S.C. § 103(a) as being unpatentable over Nenov in view of U.S. Patent No. 6,887,199 to Bridger et al. (Bridger); claims 7, 8, 13, 19, 22 and 25 under 35 U.S.C. § 103(a) as being unpatentable over Nenov in view of U.S. Patent No. 5,486,204 to Clifton (Clifton); claims 10, 11, 20 and 36 under 35 U.S.C. § 103(a) as being unpatentable over Nenov in view of U.S. Patent Application Publication No. 2002/0004729 by Zak et al. (Zak); claims 23 and 24 under 35 U.S.C. § 103(a) as being unpatentable over Nenov in view of Clifton as applied to claim 22, and further in view of U.S. Patent No. 6,277,143 to Klatz et al. (Klatz); and claims 35 and 40 under 35 U.S.C. § 103(a) as being unpatentable over Nenov in view of Klatz.

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Applicant respectfully traverses these rejections. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Initially, Applicant notes that none of the additionally cited references provide any teaching that would overcome the deficiencies of Nenov with respect to the requirements Applicant's independent claims discussed above. For at least this reason, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 4, 6-8, 10, 11, 13, 18-20, 22-25, 32, 35, 36 and 40 under 35 U.S.C. § 103(a), and the rejections of each of these claims should be withdrawn. Moreover, the applied references, either alone or in combination, fail to teach or suggest a number of the requirements recited in these claims.

For example, claim 6 requires that the selected brain injury protocol comprises one of an ischemic stroke protocol and a hemorrhagic stroke protocol. As discussed above, Nenov does not teach or suggest selecting a brain injury protocol. Further, Nenov does not even discuss ischemic or hemorrhagic stroke, much less teach or suggest an ischemic stroke protocol or a hemorrhagic stroke protocol.

The Examiner attempted to overcome the deficiencies of Nenov with respect to the requirements of claim 6 by citing Bridger. Bridger describes a blood sensor which may allow ischemic and hemorrhagic brain trauma to be distinguished. (E.g., Summary). Although Bridger, unlike Nenov, mentions ischemic and hemorrhagic stroke, Bridger does not even remotely suggest ischemic or hemorrhagic stroke protocols, or selection of protocols. Accordingly, even if Nenov and Bridger were combined in the manner suggested by the Examiner, the combination would still fail to meet the requirements of claim 6. The combination would merely result in the system of Nenov with an additional sensor, not a system that selected one of an ischemic or hemorrhagic stroke protocol based on received data concerning a patient.

As another example, claims 7, 19 and 22 further require a therapy device. The Nenov system does not deliver any therapy, or include any therapy devices. However, the Examiner argued that it would have been obvious to one of ordinary skill to modify the Nenov system to deliver therapy as taught by Clifton, either because a brain injury protocol could include therapy, or because the therapy would improve the condition of a patient with a brain injury.

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Applicant respectfully disagrees for several reasons. First, the "motivations" cited by the Examiner are simply too general to have actually motivated one of ordinary skill to modify the Nenov system as proposed by the Examiner. The Examiner's focus must be not upon what is merely feasible, but what is desirable, as suggested by the prior art as a whole. In re Fulton, 73 USPQ2d 1141, 1145 (Fed. Cir. 2004) (quoting In re Beattie, 24 USPQ2d 1040 (Fed. Cir. 1992) and Winner Int'l Royalty Corp. v. Wang, 53 USPQ2d 1580 (Fed. Cir. 2000). The mere fact that it was known that therapies could improve the condition of patients with brain injuries is not sufficient to motivate one of ordinary skill to modify any particular system to include any particular therapy, much less to modify the Nenov system to include the therapy described by Clifton. Further, the mere possibility that delivery of therapy and patient monitoring may both be done according to a protocol is not sufficient to motivate one of ordinary skill in the art to modify any particular monitoring protocol to include delivery of therapy, much less to modify the Nenov protocol to include delivery of therapy as described by Clifton.

There is no evidence in the record that one of ordinary skill in the art would have had any reason to, or seen any advantage in modifying the Nenov system to deliver any therapy, much the therapy as described by Clifton. Nenov is narrowly focused on providing a system that automatically determines the GCS score for a critically ill patients on a periodic basis. (Abstract). Further, the Nenov system is intended to be "no harder to use, nor more invasive than current monitoring for vital signs...." (Col. 5, ll. 55-57).

By way of contrast, delivery of therapy according to Clifton is invasive, requiring hypothermic cooling of the patient using a blanket, as well as delivery of a muscle relaxant and a sedative. (E.g., Summary). Consequently, therapy according to Clifton is more invasive than monitoring for vital signs. Moreover, one of ordinary skill would recognize the that cooling blanket and drugs would likely impair the patients' ability to respond to the GCS queries provided by the Nenov system, or impair the ability of the Nenov system to record responses to such queries. In other words, one of ordinary skill in the art would have recognized that modification of the Nenov system to delivery therapy according to Clifton, as proposed by the Examiner, would frustrate the operation and advantages of the Nenov system. For this reason, one of ordinary skill would have not been motivated to make such a modification, and in fact would have consciously avoided such a modification.

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For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 4, 6-8, 10, 11, 13, 18-20, 22-25, 32, 35, 36 and 40 under 35 U.S.C. § 103(a). Withdrawal of these rejections is requested.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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